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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,278	09/11/2003	William J. Carroll	000309-00049	5691

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EXAMINER	
MANUEL, GEORGE C	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
01/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,278	CARROLL ET AL.	
	Examiner	Art Unit	
	George Manuel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39 and 43-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39 and 43-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 39 and 43-46 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., applying electrical stimulation alternately between muscle groups with overlap) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Stimulation that causes actual functioning of a joint must mimic natural functioning; otherwise, the joint wouldn't function. The assumption that joint functioning causes destructive wear and tear is without merit. Joints that lack function stiffen and become more susceptible to degenerative processes. Thus, a lack of motion increases the tendency toward destructive wear and tear.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the

requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 39, 43 49, 50 and 58 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by McGraw et al (US 6,393,328).

McGraw et al clearly suggest that "the electrical stimulation is adapted to mimic a sequencing of at least two muscle groups proximate to the body segment and is sufficient to achieve forceful contraction of the at least two muscle groups." For example, col. 6, lines 17-21, teach in a pulsed muscle stimulation mode the electro-medical device 10 generates an alternating biphasic asymmetric balanced pulse pattern. Col. 5, lines 29-33, suggest the portable electro-medical device 10 provides channels that are capable of treating four separate muscle groups. Col. 6, lines 35-39 teach a train of repeating pulses is created during a contract cycle and no pulses are created during a relax cycle. Contract cycles and relax cycles are repeated until an end of treatment.

In a normal mode, four channels of the electro-medical device act synchronously, providing the stimulation pulse trains at the same time, although the intensities of each channel are independently controlled. This mode of operation allows the patient to independently treat up to four separate muscle groups simultaneously to effect a pattern of normal joint action.

Regarding claims 43, 50 and 59, in step 606, the control routine determines whether ten minutes have elapsed. If, in step 606, the control routine determines that ten minutes have not elapsed, then the control routine returns to step 594. If, however,

the control routine determines that ten minutes have elapsed, then the control routine returns to step 584.

Claims 39, 49, 57 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,165,750 ("Aleev et al.").

Aleev et al. discloses a bioelectrically controlled electric stimulation in which the sequence of the electrical stimulation corresponds to the sequence of contractions of muscles in natural conditions (see col. 1, lines 30-45). Examiner considers such sequential programming "to mimic a sequencing of at least two muscle groups proximate to the body segment" since such stimulation sequence corresponds to the sequence of contractions of muscles in natural conditions. Such stimulation is believed to restore the strength of damaged muscles and also restores lost motor skills for enabling a person to perform compound motions of the extremities, torso, and head (see col. 1, lines 25-30 and 40-45). The electric stimulator utilizes an activity sensor (2) which includes two electrodes (3) attached to a first person's skin proximate to muscles for obtaining the bioelectric activity of muscles of a person who sets a program of movements (see col. 7, 30-40 and Figure 1; see also col. 11, lines 23-35). Such program of movements is used to stimulate the muscles of a second person under control via two electrodes 19 (see col. 8, lines 15-25 and Figure 1; see also col. 11, line 62 - col. 12, line 33).

With respect to claim 57, the electrical stimulation of Aleev et al. causes the muscles to be excited and contract, and thus necessarily provides neuromuscular electrical stimulation (see, as evidence, U.S. Patent No. 5,070,873 at col. 1, lines 23-30

which describes that muscle fibers contract in response to the electrical stimulation of neural motor units).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 39 and 43-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,324,317 ("Reiss") in view of U.S. Patent No. 3,083,712 ("Keegan, Jr.").

Reiss discloses a portable inferential stimulator for producing a low frequency therapeutic current at a selected point in order to reduce pain, reduce edema and inflammation, increase blood flow, and reduce muscle spasms (see Abstract). Reiss discloses that the inferential stimulator includes a mode control to permit changing the sequence of stimulation to find the most effective pain relief (see col. 1, line 62 - col. 2, line 16). Reiss fails to specifically disclose a mode of operation in which the electrical stimulation is applied having characteristics and sequencing which mimic normal electrical sequencing of surrounding muscles of the joint during normal functioning activity. Keegan, Jr. teaches a device for producing transcutaneous electrical muscle therapy which produces sequential programming of synthetic exterior muscle

stimulation, wherein such programmed stimulation is between antagonistic muscles in a proper time relation required for normal function of the muscles (see col. 1, line 70 - col. 2, line 2). The electrical stimulation sequencing is believed to provide a movement pattern close to the movement pattern of a normal function muscle, and presents an opportunity for retraining and muscle re-education (see col. 5, line 67 - col. 6, line 3). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the sequence of stimulation of the inferential stimulator disclosed in Reiss such that the sequence of stimulation mimics normal electrical sequencing of surrounding muscles of the joint during normal functioning activity as taught by Keegan, Jr. in order to retrain and re-educate the muscle to take over normal function and control while simultaneously providing pain relief.

With respect to claims 43 and 59, Reiss discloses that the electrical stimulation includes a duration from 10 minutes to 4 hours per day (treatments of up to about 60 minutes are preferred; see col. 2, lines 20-26).

With respect to claims 44, 51 and 52, Reiss discloses that the electrical stimulation is within a range of 5 mA to 150 mA (the preferable output amperage varies from about 0 to 50 milliamps; see col. 2, lines 18-26).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is 571-272-4952. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner
Art Unit 3762